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IN THE UNITED STATES DISTRICT COURT FOR DISTRICT OF MONTANA HELENA DIVISION

THE STATE OF MONTANA, EX. REL., AUSTIN KNUDSEN, ATTORNEY GENERAL

PLAINTIFF,

V.

ELI LILLY AND COMPANY; ET AL

DEFENDANTS.

Case No. 6:22-CV-00087-BMM-JTJ

PLAINTIFF'S OPPOSITION TO MANUFACTURERS' MOTION TO DISMISS FIRST AMENDED COMPLAINT UNDER FED. R. CIV. P. 12(b)(6)

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FACTUAL ALLEGATIONS

Acting in the public interest of the State of Montana (the "State") and its citizens, the Honorable Austin Knudsen, Attorney General, filed this action against the Defendants (1) on behalf of the State's citizens who purchase diabetes medications, and (2) on behalf of the State as a payor and purchaser of diabetes medications through its state employee health plans and state-run facilities. (¶ 35)¹

Pursuant to common law and the Montana Unfair Trade Practices and Consumer Protection Act (the "MCPA") – MONT. CODE ANN. § 30-14-101, *et seq.*— the Attorney General seeks to address the harms inflicted upon the tens of thousands of diabetic Montanans who rely on the at-issue medications for survival. (¶¶ 1–4, 224).

This action challenges the pricing system for insulin and diabetes medications.

This pricing system has been (and continues to be) corrupted by the Insulin Pricing

Scheme created by two sets of actors—the Manufacturer Defendants²

¹ All references herein to (¶) are citations to the paragraphs of the First Amended Complaint (Dkt. 40), referred to herein as the "complaint."

² Manufacturer Defendants are Eli Lilly and Company ("Eli Lilly"), Sanofi-Aventis U.S. LLC ("Sanofi"), and Novo Nordisk Inc. ("Novo Nordisk"). (¶ 83). The complaint identifies the at-issue drugs in Table 1.

("Manufacturers") and the Pharmacy Benefit Manager Defendants³ ("PBMs" or "PBM Defendants").

Defendants' efforts to artificially inflate prices of the at-issue drugs would not be possible without the participation of both the Manufacturers and the PBMs. (¶ 20). The Manufacturers produce ninety-nine percent (99%) of all insulins available in the United States, including those sold in Montana. (¶¶ 5, 246) The PBMs are the largest pharmacy benefit managers in the United States and Montana, accounting for approximately 80% of the PBM market. The PBMs "dominate the pricing system" for the at-issue drugs by controlling their access to the market and by ensuring that the list prices reported by the Manufacturers influence downstream pricing for all payors and consumers, including the State and its citizens. (¶¶ 6–11, 285-288, 302-303, Figure 12 at ¶ 295). The Insulin Pricing Scheme starts with the Manufacturers' reporting of artificially-inflated and false list prices which, in turn, elevate the prices paid for the at-issue drugs by all downstream payors and purchasers, including the State and its diabetic citizens.

-

³ PBM Defendants are (a) Evernorth Health Inc., Express Scripts Inc., Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy Inc., and Medco Health Solutions Inc., collectively referred to as "Express Scripts"; (b) CVS Health Corporation, CVS Pharmacy, Inc., Caremark Rx LLC, CaremarkPCS Health, LLC, and Caremark, LLC, collectively referred to as "CVS Caremark"; and (c) UnitedHealth Group Inc., OptumRx Inc. and OptumInsight Inc., collectively referred to as "OptumRx."

Combined, the Manufacturers and PBMs have inflated insulin prices to the point of fiction and falsity. The prices for this century-old drug are not based on the cost of production, innovation, or other legitimate market forces. (¶¶ 233, 253, 358-359, 429, 517) Instead, there is no price competition between the Manufacturers; the at-issue diabetes medications are captive to "a vicious cycle of price increases" in an industry that "is anything but a free market." (¶¶ 174, 358 (OptumRx admission of "lack of meaningful competition"); ¶ 375 (findings of "2021 Senate Insulin Report")).

Utilization of the at-issue drugs is driven by the PBMs' drug formularies that determine which medications are covered by health plans. (¶¶ 7, 10-11) From this vantage, the PBMs wield enormous control over drug purchasing behavior (¶¶ 6–11, 463), and the Manufacturers pay PBMs significant sums in the form of rebates and other Manufacturer Payments to ensure the inclusion of their diabetes medications on the PBM's formularies.⁴ (¶¶ 19-20, 23, 375-376, 435). In turn, the PBMs grant preferred formulary status to the at-issue drugs with the highest (albeit, false) list prices (¶¶ 22, 365, 435, 515), and then use the false list prices to set the rate that

⁴ Manufacturer Payments are not limited to "rebates" and include administrative fees, inflation fees, pharmacy supplemental discounts, volume discounts, price or margin guarantees, etc. Such a broad definition is necessary because, PBMs frequently reclassify and rename their payment streams to avoid disclosure of their receipt of remuneration, in part or whole, that PBMs formerly labeled as "rebates." (¶ 20, n. 3).

payors and patients pay for the at-issue drugs. (¶ 350). The Insulin Pricing Scheme initiated with the PBMs' ascendancy to power in 2003, and dramatic increases in the price of the at-issue drugs soon followed. (¶¶ 264–265, 536).

The scheme is multi-faceted: First, to secure formulary access, the Manufacturers artificially inflate the prices of their diabetes medications to finance significant Manufacturer Payments made to the PBMs. (¶¶ 20, 344, 348, 376). Second, the Manufacturers publicly report the false list prices to publishing compendia in the industry, with knowledge that the prices they report will escalate the prices paid by the State and its citizens.⁵ (¶¶ 422, 426–429, 513) Third, PBMs falsely represent that their formularies are used to negotiate lower prices from the Manufacturers. (¶¶ 351–352, 437–438, 441–442)

The deception is stark. The Manufacturers report artificially-inflated prices, and the PBMs misuse their formularies to capture the increased Manufacturer Payments which flow therefrom, despite the PBMs' repeated representations that

⁵ The Wholesale Acquisition Cost ("WAC"), which the Manufacturers report, is the starting point for all downstream pricing metrics in the pharmacy pricing chain. The WAC price is mathematically-related to the Average Wholesale Price ("AWP") (¶¶ 285-288), which is typically set at a premium of 20% to 25% higher than the reported WAC. *In re Pharmaceutical Industry Average Wholesale Price Litig.*, 491 F.Supp.2d 20, 33 (D. Mass. 2007). While it is true that different actors pay different prices for the same drugs, the AWP and all other downstream prices derive from the reported WAC; the unifying factor is that the price paid by each payor/consumer in the pharmaceutical pricing chain is elevated as a result of the false WAC list prices generated by the Insulin Pricing Scheme. (¶ 285).

their businesses are modeled on lowering costs. (¶¶ 175, 375 ("2021 Senate Insulin Report," finding that the "vicious cycle of price increases" of insulin is attributable to "PBMs spur[ring] drug makers to hike list prices in order to secure prime formulary placement and [pay] greater rebates and fees").

The United States Senate's January 2021 Report on insulin pricing, entitled "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug," was released after the U.S. Senate reviewed over one hundred thousand pages of the Defendants' internal documents. (¶¶ 342-343) The 2021 Senate Report was the first reliable investigation of the Insulin Pricing Scheme, and among other things, confirmed certain facts essential to the State's claims, including that rebates on insulin products had escalated from single digit percentages to 50% or greater of the reported WAC price (¶ 345); that the sharp escalation in insulin prices is not the result of legitimate expenses for drug research and development or improvements in efficacy of diabetes medications (¶ 374); and that Manufacturer Payments are the primary culprit for the artificial inflation of insulin and diabetic drug prices. (¶ 375).

⁶ See, U.S. Senate Comm. on Finance, Grassley, Wyden Release Insulin Investigation, Uncovering Business Practices Between Drug Companies and PBMs That Keep Prices High, Jan. 14, 2021, https://www.finance.senate.gov/chairmansnews/grassley-wyden-release-insulin-investigation-uncovering-business-practices-between-drug-companies-and-pbms-that-keep-prices-high. See Friends of the Flathead River v. U.S. Forest Serv., No. 22-cv-90, 2022 WL 2751772, at *6 n.2 (D. Mont. July 14, 2022) (court may take judicial notice of publications as indication of information in public realm).

The State alleges that each of the Manufacturers misrepresented the actual prices of their diabetes medications and reported and published the false prices in furtherance of the scheme. (¶¶ 287, 426-429, 434-435). The State further alleges that the reported prices were not legal, competitive, or representative of fair market value, and were so untethered from the actual prices received by the Manufacturers as to be false. (¶¶ 21, 349, 424, 513, 516). As a result, the State and diabetic Montanans have overpaid for the at-issue drugs by millions of dollars a year. (¶¶ 28–29).

Since 2003, the reported prices of certain of the at-issue medications have increased by more than 1000%, far outpacing the rate of medical inflation (46%) over the same time period. (¶ 266). The price escalation has been marked by the Manufacturers' "lockstep rais[ing] [of] the reported prices," "despite the fact that the cost to produce these drugs has decreased during [the] same time period." (¶¶ 13). The skyrocketing prices are not justified by any scientific advances or innovations—today's insulins are the same or biologically equivalent to those available in the late 1990s. (¶ 251-252 (citing 2018 JAMA study)).

⁷ Contrary to the Manufacturers' contention, the complaint does <u>not</u> allege that the Manufacturers accurately or correctly reported their list prices. The State's pleading is replete with allegations that the reported prices are false. (¶¶ 19 ("artificially inflated"), 21 ("false"), 53 ("artificially inflated list prices") 289 ("false and deceptive"), 349 ("false and unlawful"); and 411 ("false prices"))

ARGUMENT

I. LEGAL STANDARDS

A. Rule 12(B)(6)

To survive a Rule 12(b)(6) motion, the Complaint must contain sufficient factual matter to state a claim for relief that appears plausible on its face. *Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009). A claim appears plausible on its face when "the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 678.

The Court must accept all allegations of material fact contained in the complaint as true when evaluating a Rule 12(b)(6) motion. *Johnson v. Lucent Technologies Inc.*, 653 F.3d 1000, 1010 (9th Cir. 2011). The Court does not weigh the facts at the Rule 12(b)(6) stage, but merely assesses the sufficiency of Plaintiff's allegations. *See Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556 (2007). The Court must look at the facts in the light most favorable to the Plaintiff when considering a motion to dismiss for failure to state a claim. *Iqbal*, 556 U.S. at 685.

II. HEIGHTENED PLEADING IS NOT REQUIRED FOR ALL MCPA CLAIMS

The MCPA is modeled on the Federal Trade Commission Act ("FTC Act"), 15 U.S.C.A. § 45(a)(1).8 MONT. CODE ANN. § 30-14-104(1) & (2) (due consideration

⁸ 15 U.S.C.A. § 45(a)(1) declares unlawful "[u]nfair methods of competition [and] unfair or deceptive acts or practices" in or affecting commerce. The purpose of 15

and weight should be given to federal courts' interpretation of FTC Act; prohibiting promulgation of rules inconsistent with those of the Federal Trade Commission); *Britton v. Farmers Ins. Group*, 721 P.2d 303, 323 (Mont. 1986) (prohibiting MCPA interpretations inconsistent with FTC Act rules, regulations and case law).

Claims brought under the FTC Act are not claims for fraud, even though some element of deception may be involved. *FTC v. Hornbeam Special Situations, LLC,* 308 F. Supp. 3d 1280, 1287 (N.D. Ga. 2018) (FTC Act does not require proof of scienter, reliance or injury to establish a violation). Federal courts do not apply the heightened pleading standard of FED. R. CIV. P. 9(b) to FTC Act claims, and instead, apply the FED. R. CIV. P. 8 pleading standard. *Hornbeam,* 308 F. Supp. 3d at 1287; *FTC v. HES Merch. Servs. Co.,* No. 12-cv-1618, 2014 WL 12611275, at *2 (M.D. Fla. Feb. 20, 2014) (rejecting Rule 9(b), but noting split of authority on the issue).

Application of Rule 8's pleading standard is obvious where the allegations do not require proof of deceit. *See In re Cattle Antitrust Litig.*, 2021 WL 7757881, at *12 n. 22 (D. Minn. Sept. 14, 2021) (refusing to apply Rule 9(b) to a MCPA claim based on anticompetitive conduct); and *In re Broiler Chicken Antitrust Litig.*, 290 F.

U.S.C.A. § 45 is "to eliminate unfair competition and practices which if left untouched will inevitably become the evils prohibited by the Sherman [Antitrust] Act." *Homefinder's of America, Inc. v. Providence Journal Co.*, 471 F. Supp. 416, 423 (D. R.I. 1979).

Supp. 3d 772, 820 (N.D. Ill. 2017) (rejecting application of Rule 9(b) to a claim brought under MCPA's "unfair[ness] prong").

As this Court has recognized, the MCPA "does not limit itself to deception-based conduct." *Haskett v. American Home Centers, LLC,* No. 21-cv-68, 2022 WL 11805576, at *4 (D. Mont. Oct. 20, 2022). The MCPA "reaches more broadly than mere deception" and prohibits "unfair act[s] or practice[s]" which offend public policy and cause serious injury. *Id., citing Anderson v. ReconTrust Co., N.A.*, 407 P.3d 692, 700 (Mont. 2017). Consequently, Rule 9(b) is not applicable to the State's "unfair" trade practice claim against the Defendants.

Even if Rule 9(b) applies to certain of the State's claims (*e.g.*, the "deceptive" trade practice claim), the allegations in the complaint far surpass the particularity standard. Any issue regarding adequacy of the State's Insulin Pricing Scheme allegations has been laid to rest by the rulings of multiple district courts. *See, Mississippi ex rel. Fitch v. Eli Lilly & Co.*, No. 21-cv-674, 2022 WL 3222890, at *6 (S.D. Miss. Aug. 9, 2022) (Mississippi's 118-page complaint delineates each Manufacturer's participation in the "Insulin Pricing Scheme," including specific drugs, prices, timelines, knowledge, and intent, and sufficiently asserts the "who, what, when, where, and how" of the alleged misconduct); *Harris Cnty., Texas v. Eli Lilly & Co.*, No. 19-cv-4994, 2020 WL 5803483, at *5 (S.D. Tex. Sept. 29, 2020)

(Insulin Pricing Scheme allegations satisfied Rule 9(b)); Minnesota by Ellison v. Sanofi-Aventis U.S. LLC, No. 18-cv-14999, 2020 WL 2394155, at *17 (D.N.J. Mar. 31, 2020) (reaching same conclusion with respect to adequacy of Insulin Pricing Scheme allegations); and In re Insulin Pricing Litig., No. 17-cv-699, 2019 WL 643709, at *14-15 (D.N.J. Feb. 15, 2019) (Insulin Pricing Scheme allegations satisfied Rule 9(b) particularity requirement).

III. THE STATE'S ALLEGATIONS STATE CLAIMS UNDER THE MCPA

A. The MCPA Broadley Protects Consumers From Unfair Or Deceptive Trade Practices

Montana's courts liberally construe the MCPA to effectuate its purpose of "protect[ing] the public from unfair or deceptive practices." *Tripp v. Jeld-Wen, Inc.*, 112 P.3d 1018, 1026 (Mont. 2005); *Baird v. Norwest Bank*, 843 P.2d 327, 333 (Mont. 1992). Consumer protection statutes such as the MCPA have been interpreted as "broad in scope and flexible in application so as to respond to human inventiveness." *McCollough v. Johnson, Rodenberg & Lauinger*, 610 F. Supp. 2d 1247, 1251 (D. Mont. 2009).

⁹ The district court in *Harris Cnty*. later dismissed plaintiff's claims based on the direct purchaser rule established under *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977). Defendants have not asserted this defense in the instant action. The ruling of the *Harris Cnty*. district court on the Rule 9(b) issue remains undisturbed.

Thus, it is unsurprising that liability under the MCPA does not require privity of contract [McCollough, 610 F. Supp. 2d at 1252], or proof of an intent to deceive [Young v. ERA Advantage Realty, 513 P.3d 505, 513 (Mont. 2022)], or even a pre-existing legal duty. Id. And, when unfair trade practice claims are brought on the basis of artificial or fictitious pricing, purchase of the product at the unlawful price constitutes all of the consumer reliance that is necessary. See, In re Auto. Parts Antitrust Litig., No. 12-md-2311, 2014 WL 3687035, at *3 (E.D. Mich. July 23, 2014) (unfair trade practice claims based on an illegal conspiracy to raise prices that "created damage at the time of purchase"); In re Pork Antitrust Litig., 495 F. Supp. 3d 753, 781 (D. Minn. 2020) (denying dismissal of unfair trade practice claims because "[p]laintiffs did not have to rely on anything to suffer damages; they had only to pay allegedly inflated prices").

It is equally settled that consumer protection violations may arise out of a party's participation in seemingly lawful activities. *Shell Oil Co. v. FTC*, 360 F.2d 470, 479 (5th Cir. 1966) (finding that a commission sales agreement, though not illegal *per se*, constituted unfair method of competition); *FTC v. Algoma Lumber Co.*, 291 U.S. 67, 80 (1934) (the practice does not have to amount to "a fraud as understood in courts of law"); and *Spiegel, Inc. v. FTC*, 540 F.2d 287, 292 (7th Cir. 1976) (FTC has the authority to prohibit conduct that, although legally proper, is unfair to the public.).

Montana law is consistent with FTC jurisprudence on this issue. In *Mitchell v. First Call Bail and Surety, Inc.*, 412 F. Supp. 3d 1208 (D. Mont. 2019), an arrestee brought a MCPA claim against a bail bonding company. Rejecting the defendant's argument that "commercial bail bond transactions are lawful in Montana," the court held that plaintiff adequately stated a claim that "this particular transaction" was "unfair" as the result of several factors, including his lack of opportunity to understand the agreement and his lack of bargaining power. *Id.* at 1221. The Manufacturers' argument about the legality of rebates should be similarly viewed the issue is not the legality of rebates *per se*, but whether the Defendants artificially inflated insulin prices through the use of rebates or other pricing mechanisms.

B. MCPA Unfairness And Deception Are Distinguished By Their Rationales

A deceptive act under the MCPA is one that is likely to mislead consumers. *Young*, 513 P.3d at 513. "[F]alse representations as to the characteristics, use, or benefits of what is being sold" may constitute a deceptive act. *Id*.

"[A]n unfair act or practice is one which offends established public policy and which is either immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers." *Rohrer v. Knudson*, 203 P.3d 759, 764 (Mont. 2009). This definition is patterned on the United States Supreme Court's decision *FTC v. Sperry* & *Hutchinson Co.*, 405 U.S. 233, 244 n.5 (1972) which interpreted the meaning of "unfairness" as set forth in the FTC Act. *Rohrer*, 203 P.3d at 764.

Consumer protection actions may involve elements of both unfairness and deception, but these are independent bases of liability. See American Financial Services Ass'n v. FTC, 767 F.2d 957, 979 n.27 (D.C. Cir. 1985) ("[T]he two rationales are distinct: A practice is deceptive when the consumer is forced to bear a larger risk than expected (e.g., the consumer is misled) whereas a practice is unfair when the consumer is forced to bear a larger risk than an efficient market would require.") (emphasis added).

To provide examples of unfair or deceptive conduct, the MCPA authorized the Montana Department of Justice to promulgate a non-exhaustive list of certain trade practices deemed to be unlawful under Mont. Code Ann. § 30-14-103. *Anderson*, 407 P.3d at 700; Mont. Admin. R. 23.19.101(2) (rules "not intended to be exhaustive").

The resulting regulation—MONT. ADMIN. R. 23.19.101(1)—states that a person engages in "unfair or deceptive and therefore unlawful acts or practices" when, in the conduct of any trade of commerce, he: (1) makes a false representation as to the "characteristics" of merchandise [MONT. ADMIN. R. 23.19.101(1)(e)]; (2) makes false and misleading statements of fact concerning the price of merchandise or the reason for existence of, or amounts of a price reduction [MONT. ADMIN. R. 23.19.101(1)(k)]; (3) states that a transaction involves rights, remedies or obligations

that it does not involve [MONT. ADMIN. R. 23.19.101(1)(i)]; or (4) employs deceptive pricing practices. MONT. ADMIN. R. 23.19.101(1)(p).

While the regulation speaks to deception ("false representation," "misleading statements"), it also seeks to protect the efficiency and fairness of relevant markets ("price," "price reduction," "pricing practices"). Moreover, the plain language of MONT. ADMIN. R. 23.19.101(1) establishes that artificial and false pricing constitutes a violative of Montana public policy. ¹⁰

C. Plaintiff's MCPA Claims Are Legally Cognizable

The State's Complaint alleges that the Manufacturers violated the MCPA by, among other things, artificially inflating the list prices of insulin and diabetes medications, making false representations about the characteristics (*i.e.*, list prices) of the same in reporting those prices to industry publishing compendia, and concealing from the State and its citizens that the published prices were artificial and false. (¶ 513).

FTC Act jurisprudence establishes that fictitious pricing is both deceptive and unfair. *See Spiegel, Inc. v. FTC,* 411 F.2d 481, 483 (7th Cir. 1969) (fictitious price "constitutes a material influence on the consumer's decision to purchase" and has "long been held a deceptive practice"); *FTC v. American Financial Benefits Center,*

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¹⁰ Montana's public policy accords with federal courts' interpretation of the FTC Act. *See Regina Corp.*, 322 F.2d at 770 ("There is no constitutional right to promulgate and distribute fictitious suggested list prices.").

324 F. Supp. 3d 1067 (N.D. Cal. 2018) (representation regarding fixed monthly payments was false); *Giant Food Inc. v. FTC*, 322 F.2d 977, 982 (D.C. Cir. 1963) (fictitious "manufacturer's list price" was false and deceptive); *Regina Corp. v. FTC*, 322 F.2d 765, 768 (3d Cir. 1963) (manufacturer's dissemination of fictitious list prices constituted "unfair and deceptive" practice); *Helbros Watch Co. v. FTC*, 310 F.2d 868, 869 (D.C. Cir. 1962) (list prices at 400% to 500% of cost constituted fictitious, illegal pricing); and *DeGorter v. FTC*, 244 F.2d 270, 281 (9th Cir. 1957) (manufacturer's pricing system bore the "badge of deceit"). ¹¹

In line with the FTC Act, courts have approved use of the MCPA to address instances of overbilling, excessive charges, and the artificial inflation of prices. *See Staley v. Gilead Sciences, Inc.*, 446 F. Supp. 3d 578, 642 (N.D. Cal. 2020) (plaintiffs stated a claim under the MCPA for artificial price inflation of HIV medications); *Sides v. Global Travel Alliance, Inc.*, No. 20-cv-53, 2021 WL 5926136, at *10 (D.

The FTC's vigilance to enjoin fictitious pricing is rooted in its policy of protecting unsophisticated consumers who are not cognizant of complex pricing structures. A method inherently unfair does not cease to be so because the falsity of the public representation has become so well known to those engaged in identical or similar enterprises as to no longer deceive them. *Ford Motor Co. v. FTC*, 120 F.2d 175, 182 (6th Cir. 1941). "The [FTC Act] was not intended to protect sophisticates." *Giant Food*, 322 F.2d at 977. "Fictitious prices are illegal even though it is obvious to the sophisticated that the price tag is only a come-on. The law is not made for the protection of experts, but for the public – the vast multitude which includes the ignorant, the unthinking and the credulous, who, in making purchases, do not stop to analyze, but are governed by appearances and general impressions." *Id.* at 982, n. 13.

Mont. Aug. 16, 2021) (MCPA claim stated where travel company manipulated contracts to withhold full refunds from consumers); *Wittman v. CB1, Inc.*, No. 15-cv-105, 2016 WL 3093427, at *6 (D. Mont. June 1, 2016) (plaintiffs who were charged unauthorized credit card fees stated a claim under MCPA). Likewise, the Montana Supreme Court has held that the overbilling of consumers is within the scope of the MCPA. *Hein v. Sott*, 353 P.3d 494, 499 (Mont. 2015) (homeowner stated a claim for a consumer protection violation against his contractor who billed for work not performed).¹²

And, with respect to insulin specifically, publishing, utilizing, and promoting artificially-inflated prices has been held to constitute a fraudulent or deceptive act. ¹³

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¹² Additional courts have refused to dismiss MCPA claims alleging price-fixing or the artificial inflation of prices. See, e.g., In re Hard Disk Drive Suspension Assemblies Antitrust Litig., No. 19-md-2918, 2021 WL 4306018, at *23 (N.D. Cal. Sept. 22, 2021) (allegation of "inflated prices"); In re Cattle Antitrust Litig., 2021 WL 7757881, at *15 (alleged conspiracy to generate "historically unprecedented profit"); In re Remicade Antitrust Litig., 345 F. Supp. 3d 566, 590 (E.D. Penn. 2018) (allegations that drug manufacturer utilized rebate agreements to "artificially inflate prices"); In re Broiler Chicken Antitrust Litig., 290 F. Supp. 3d at 820 (alleged conspiracy to cut production in order to "inflate prices"); and In re Automotive Parts Antitrust Litig., 50 F. Supp. 3d 836, 861 (E.D. Mich 2014) (allegation that defendants "unlawfully fix[ed] and artificially raise[d] prices").

¹³ See, City of Miami v. Eli Lilly & Co., No. 21cv-22636, 2022 WL 198028, at *8 (S.D. Fla. Jan. 21, 2022); In re Direct Purchaser Insulin Pricing Litig., No. 20-cv-3426, 2021 WL 2886216, at *14–15 (D.N.J. July 9, 2021); Harris Cnty., 2020 WL 5803483, at *16; Minnesota, 2020 WL 2394155, at *17; MSP Recovery Claims, Series, LLC v. Sanofi-Aventis U.S. LLC, No. 18-cv-2211, 2019 WL 1418129, at *19 (D.N.J. Mar. 29, 2019); and Insulin Pricing Litig., 2019 WL 643709, at *14-15.

These decisions are consistent with FTC principles, MONT. ADMIN R. 23.19.101(1), and the purpose of the MCPA.

D. Plaintiff's Pleading Alleges Adequate Particularized Facts

Even under Rule 9(b), the State's Complaint satisfies the heightened pleading standard. The State's pleading does not, as the Manufacturers contend, inappropriately "lump" them together. With respect to their involvement in the Insulin Pricing Scheme, the Complaint specifically identifies each of the Manufacturers by conduct, drugs, pricing, dates, and testimonial or other admissions.

Among other things, the complaint alleges:

- drugs as a direct result of negotiations and agreements with the PBMs (¶¶ 362–374) and with knowledge that the State and Montanans pay for the at-issue drugs based on these list prices. (¶¶ 22, 285–288, 350, 435). Manufacturers published and reported these list prices in the United States and Montana and these prices were utilized by pharmacies and other downstream entities to set the prices paid by the State and Montana diabetics. (¶¶ 426-428);
- (2) The Manufacturers artificially and arbitrarily inflated the list prices as part of the Insulin Pricing Scheme, such that these prices

were false, not tethered to any competitive or fair market value, and did not bear a reasonable relationship to the actual prices which the Manufacturers realized on the sale of the at-issue drugs. (¶¶ 20-21, 51, 65, 79, 344, 345, 422-424, 428-429, 455). Artificial price inflation by the Manufacturers was *quid pro quo* for inclusion of the at-issue drugs on the PBMs' formularies. (¶ 20, 363).

- (3) The Complaint specifically identifies the at-issue medications involved in the Insulin Pricing Scheme by name, manufacturer, and current price. (¶ 263, Table 1). The Complaint presents specific examples of the price increases by each Manufacturer by drug, date, and the amount/percentage of price increase. *See* Figures 1-6. In thirteen instances since 2009, and pursuant to the Insulin Pricing Scheme, the Manufacturers have increased their respective prices of the at-issue drugs in lockstep, even though their costs of production have decreased over the same time period. (¶¶ 13, 275-281). *See*, Figures 7-9, 11 (¶¶ 278-279, 281);
- (4) Executive-level officers or representatives of the Manufacturers and/or PBMs have admitted, before the United States Congress or in other forums, that the price of insulin has increased dramatically in the past fifteen years (¶ 357-358, admissions by all

Defendants); that there is a "lack of meaningful competition" in the insulin market (¶ 358, admission by OptumRx's Chief Medical Officer); that diabetics lack "affordable access" to insulin (¶ 358, admission by Eli Lilly Senior Vice President); and that the "[reported] price" of insulin matters to both insured and uninsured diabetics (¶ 358, admission by Novo Nordisk Executive Vice President); and

(5) The Manufacturers, through their officers and representatives, have admitted to engaging in the overt acts which mark the Insulin Pricing Scheme: Novo Nordisk admission that "we've been participating in [the insulin pricing system] because the higher the [reported] price, the higher the rebate," (¶ 362); Sanofi admission that "rebates generated through negotiations with PBMs are being used to finance other parts of the healthcare system and not to lower prices to the patient," (¶ 364); and Eli Lilly admission that it raised its reported prices for insulin as quid pro quo for formulary position, since "[s]eventy-five percent of our [reported] price is paid for rebates and discounts to secure [formulary position]." (¶ 363).

The State alleges that the Insulin Pricing Scheme offends public policy (¶ 517) and pleads facts which implicate the consumer abuse factors set forth in *Rohrer*, 203 P.3d at 764 ("immoral, unethical, oppressive, unscrupulous or substantially injurious

to consumers"). The Manufacturers produce nearly every vial of insulin available in Montana. (¶ 517). Tens of thousands of Montana's citizens rely on insulin and diabetic medications to survive (¶ 4) and to avoid diabetes-related complications such as blindness, kidney failure, and amputation. (¶ 2). The Defendants' inflated and false prices have forced many Montana diabetics to ration or under-dose their insulin, inject expired insulin, and even starve themselves in an attempt to control their blood sugars. (¶ 30). Further, the State and its citizens have overpaid millions of dollars for the drugs in issue. (¶ 517).

There is no conceivable benefit to the State or its citizens in being forced to pay the Defendants' artificially-inflated prices, and Montanans who are diabetic are unable to protect their interest since they have no choice but to purchase the Manufacturers' diabetic drugs at false and inflated prices. (¶ 517). These factual allegations present, at a minimum, issues of morality, ethics, oppression, and substantial consumer injury. *See also* Plaintiff's Opposition to Pharmacy Benefit Managers' Motion to Dismiss at 11-15 (explaining why Defendants' misconduct was unfair), incorporated herein.

IV. MANUFACTURERS' DEFENSES ARE UNAVAILING

A. Medicare Payment Methodologies Are Irrelevant, But The Manufacturers Still Fail To Comply With The Same

Citing 42 U.S.C.A. § 1395w-3a, the Manufacturers argue they cannot be held liable for price-reporting misrepresentations because they exclude "rebates"

from their reported wholesale acquisition costs ("WACs"). For this, the Manufacturers rely on a WAC definition found in a Medicare payment methodology statute. The State and its citizens make no claims in this case which implicate Medicare, or Medicaid, and courts have ruled that this payment methodology statute is not relevant to actions which assert the Insulin Pricing Scheme. See Minnesota, 2020 WL 2394155, at *14 (state statute having the same language as § 1395w-3a was irrelevant to the deceptiveness of non-Medicaid pricing representations); Harris Cnty., 2020 WL 5803483, at *6 ("[H]ow the United States chooses to pay for [Medicare] reimbursed drugs" under the statute is "irrelevant to the deceptiveness of [the] non-[Medicare] pricing representations at issue."); and City of Miami, 2022 WL 198028, at *8, n.8 ("[T]he City's claim is that the Manufacturer[s] inflated the price of insulin and other medications through the use of fraudulent rebates that served as kickbacks to the PBM Defendants. The Manufacturer[s] cannot use Section 1395w-3a(c)(6)(B) to avoid the City's allegations of wrongdoing."). 14

¹⁴ For the same reasons, the Manufacturers' argument that 42 U.S.C.A. § 1396r-8(a)(1) requires them to pay rebates to the States should not be well taken. Section 1396r-8 has application only to Medicare and Medicaid, and this action concerns neither program.

In addition to being irrelevant, the Manufacturers' argument is also rebuttable. First, the State's complaint focuses on the role that Manufacturer Payments, not just rebates, play in the larger Insulin Pricing Scheme. Manufacturer Payments also include administrative fees, inflation fees, pharmacy supplemental discounts, volume discounts, price or margin guarantees, and any other form of consideration exchanged between the Manufacturers and PBMs. (¶ 20, n. 3). The term "rebates" as used in 42 U.S.C.A. § 1395w-3a(c)(6)(B) does not capture all of the other forms of remuneration involved in the Insulin Pricing Scheme.

Second, any statute, including 42 U.S.C.A. § 1395w-3a(c)(6)(B), must be read as a whole. "[I]n construing [a] statute, every word, clause and sentence must be given effect, if it is possible to do so, to the end that its different provisions may be made consistent and harmonious and each be assigned an intelligent meaning." *State ex rel. Interstate Lumber Co. v. District Court,* 172 P. 1030, 1031 (Mont. 1918); *Wangerin v. Department of Revenue*, 521 P.3d 36, 44 (Mont. 2022). Applying this basic tenet of statutory construction raises the question of how 42 U.S.C.A. § 1395w-3a(c)(6)(B) even applies to payments made to PBMs.

The Manufacturers admit they sell medications to wholesalers, and sometimes pharmacies, as direct purchasers—not to PBMs. (Dkt. 85 at 11). The definition in 42 U.S.C.A. § 1395w-3a(c)(6)(B) applies in the context of sales "to wholesalers or direct purchasers," not to the PBMs which are third-party strangers to such direct

purchaser transactions. Any other reading of the statute would render the words "wholesalers or other direct purchasers" superfluous.

This underscores the State's claim—the Manufacturer Payments in issue are not the type of discounts or price reductions to the wholesalers or direct purchasers which 42 U.S.C.A. § 1395w-3a(c)(6)(B) envisions; rather, the rebates in issue are undisclosed amounts which the Manufacturers pay to PBMs to secure formulary access and which the Manufacturers use to inflate, not reduce, their list prices.¹⁵

The Manufacturers' Memorandum cements their position on how rebates are to be treated under Medicare's WAC definition and MONT. CODE ANN. § 33-2-2402(14)¹⁶ - rebates which the Manufacturers pay to the PBMs <u>must be excluded</u> from the Manufacturers' reported list prices. *See* Dkt. 85 at 32 (federal law and Montana law *require* the Manufacturers to report list prices that do *not* reflect rebates); at 37 ("federal and Montana statutes require the Manufacturers to omit

¹⁵ Recent rulemaking by the U.S. Dept. of Health and Human Services indicates that rebates granted to direct purchasers will be within the federal safe harbor and recognizes that post-transaction rebates, such as those which the Manufacturers pay to the PBMs, "may create a perverse incentive that rewards manufacturers for increasing their list price, while subjecting consumers to higher out-of-pocket costs." *See*, U.S. Dept. of Health and Human Services, *Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals*, 85 Fed. Reg. 76666, 76667 (Nov. 30, 2020).

¹⁶In January 2022, Montana passed the Montana Pharmacy Benefit Manager Oversight Act ("PBMOA"), MONT. CODE ANN. § 33-2-2401, *et seq.* MONT. CODE. ANN. § 33-2-2402 (14) of the PBMOA defines "wholesale acquisition cost" as having "the meaning provided in 42 U.S.C.A. § 1395w-3a."

rebates and other payments from their WACs"); at 12 (federal and Montana law expressly require a 'manufacturer's list price' to 'not include[e]" rebates); and at 32 ("No reasonable consumer would have thought that WACs include rebates when ... federal and state law expressly provide that they cannot. Indeed, a reasonable consumer would have been misled if the Manufacturers did publish WACs that reflect rebates, in contravention of the law.")

Under the State's allegations, the Manufacturers definitely include—not exclude—rebates they pay to the PBMs in their reported list prices. Their noncompliance with the WAC definition they claim to apply results in the artificial inflation of the Manufacturer's list prices, which they report at least annually to industry publishing compendia. (¶¶ 20-22, alleging artificial inflation of list prices in order to make rebate and other Manufacturer Payments to the PBMs, and ¶¶ 426-427, alleging reporting of the artificially-inflated prices to industry publishing compendia and throughout Montana). By their own admission, the list prices which the Manufacturers report and publish are misleading to reasonable consumers.

B. The State's Pleading States A Claim For Unjust Enrichment

Unjust enrichment is an equitable claim for restitution to prevent or remedy inequitable gain by another. *Associated Management Services, Inc. v. Ruff*, 424 P.3d 571, 595 (Mont. 2018). Under Montana law, unjust enrichment does not necessarily

requires proof of underlying wrongful acts or conduct. *Id.* Unjust enrichment merely requires proof that a party unjustly gained something of value, regardless of wrongful conduct. *Id.*, *citing Northern Cheyenne Tribe v. Roman Catholic Church*, 296 P.3d 450, 457 (Mont. 2013) (noting that a court measures restitution remedies by the defendant's gain).

The essential elements of an unjust enrichment claim are: (1) a benefit conferred on one party by another; (2) the other's appreciation or knowledge of the benefit; and (3) the other's acceptance or retention of the benefit under circumstances that it would render it inequitable for the other to retain the benefit without compensating the first party for the value of the benefit. Ruff, 424 P.3d at 595. The State has alleged facts which establish these essential elements. The Manufacturers have received billions of dollars in revenue from sale of the at-issue drugs (\P 46-47 as to Eli Lilly, \P 60-61 as to Sanofi, \P 74-75 as to Novo Nordisk); the Manufacturers knew that consumers relied on the list prices they reported in purchasing the drugs (¶ 422); the Manufacturers retained revenue which the sales to consumers generated despite their engagement in unfair and inequitable practices which artificially inflated their list prices, causing the State and Montana diabetics to overpay by millions of dollars. (¶¶ 27-28). 17

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¹⁷ It is not necessary that revenue flow directly, as opposed to indirectly, from the State and Montanans to the Manufacturers. *See Diamond v. Hogan Lovells US LLP*,

Further, the Complaint sufficiently alleges that benefits were conferred upon the Manufacturers. The State alleges that the Insulin Pricing Scheme created enormous profits for all Defendants, including the Manufacturers (¶ 354) and cites studies, including the 2021 Senate Insulin Report, which demonstrate that the Manufacturers retained more revenue from sales than they did in the early 2000s, resulting in billions of dollars of distributions to their shareholders. (¶¶ 373-374). Over the same period, the Manufacturers spent only a fraction of this revenue on research and development costs for their insulin and diabetes medications. (¶ 258). Not only did the Manufacturers maintain their net prices by engaging in the Insulin Pricing Scheme (¶ 344), they immensely profited.

Unjust enrichment is not available where there is a valid and relevant contract between the parties [Ruff, 424 P.3d at 595], but this point of law is of no consequence to the Manufacturers, which admit they had no contract with the State or its citizens. Dkt. 85 at 41. For purposes of defeating the State's unjust enrichment claim, the Manufacturers cite no authority which allows them to "piggyback" on contracts which the State may have had with other parties.

⁸⁸³ F.3d 1140, 1146 (9th Cir. 2018), citing Restatement (Third) of Restitution and Unjust Enrichment, § 48 (2011); see also Griffin v. HSBC Mortgage Services, Inc., No. 14-cv-132, 2016 WL 1090578, at *19 (N.D. Miss. Mar. 18, 2016) (not required that unjustly enriched party receive funds directly from the plaintiff). Whether the Manufacturers' receipt of benefits was direct or indirect, the Manufacturers assuredly profited, as they would have no market and have received no revenue but for purchases of their drugs by end-users.

Additionally, the State disagrees that it is required to prove the existence of an "implied" contract in order to recover under unjust enrichment. Even so, the State and its citizens were the intended target of the inflated list prices reported by the Manufacturers, who knew that such false pricing would cause the State and its citizens to experience higher prices at retail and mail-order pharmacies; yet, the Manufacturers received and accepted the benefits of these sales nonetheless. *See, Mississippi,* 2022 WL 3222890, at *8 ("the State plausibly alleges an unjust enrichment claim based on the Manufacturer Defendants' alleged participation in the Insulin Pricing Scheme").

Finally, the Manufacturers' argument that unjust enrichment is unavailable where there is an adequate remedy at law overlooks the statutory rights granted to the Attorney General by the MCPA. In addition to authorizing the Attorney General to seek restitution, MONT. CODE ANN. § 30-14-131(3), , authorizes the court to "enter any other order or judgment required by equity to carry out" the statute's provisions. Hence, the right to equitable relief under the MCPA is not limited to private actions brought by consumers, as the Manufacturers incorrectly contend by their citation to MONT. CODE ANN. § 30-14-133(1).

C. The State Has Stated A Claim For Civil Conspiracy

The State's Complaint alleges that the Manufacturers and PBMs coordinated their efforts and "agreed to and participated in" the Insulin Pricing Scheme" (¶ 354),

and plausibly asserts a claim for civil conspiracy against the Defendants. (¶¶ 534-537). The facts in support thereof, alleged by the State, describe a course of conduct which plausibly suggests, if not establishes, the existence of a conspiratorial agreement.

Under Montana law, the elements of civil conspiracy are (1) two or more persons; (2) an object to be accomplished; (3) a meeting of the minds on the object or course of action; (4) one or more unlawful overt acts; and (5) damages as a proximate result thereof. *Sullivan v. Cherewick*, 391 P.3d 62, 68 (Mont. 2017). The third element—a meeting of the minds—does not require an agreement to use "unlawful means; rather, it is sufficient if minds meet on the object to be accomplished or on the course of action. *Id.* Because direct evidence of a meeting of the minds is difficult – if not impossible – to obtain, circumstantial evidence may be used to establish this element of civil conspiracy. *Schumacker v. Meridian Oil Co.*, 956 P.2d 1370, 1374 (Mont. 1998).

Civil Conspiracy requires an underlying tort or wrong. *Id.*; *Hughes v. Pullman*, 36 P.3d 339, 344 (Mont. 2001). Here, the State appropriately anchors its civil conspiracy claim on the underlying wrongs of artificially inflating and reporting false list prices, in violation of the MCPA and the doctrine of unjust enrichment.

Under *Twombly*'s plausibility requirement, plaintiffs are not held to a probability standard in pleading conspiracy and must only allege enough to raise a

reasonable expectation that discovery will reveal evidence of an illegal agreement. *Twombly*, 550 U.S. at 556; *Anderson News, LLC v. Am. Media Inc.*, 680 F.3d 162, 184 (2d Cir. 2012) (plaintiff need not show that its conspiracy allegations are more likely than not true, or exclude the possibility of independent action by the defendants). Because direct evidence of the existence of an agreement is rare, it is possible to infer the existence of an agreement from consciously parallel conduct if the parallelism is accompanied by substantial additional evidence – often referred to as the "plus factors." *In re Tyson Foods, Inc. Securities Litig.*, No. 15-cv-5340, 2018 WL 1598670, at *9 (W.D. Ark. Mar. 31, 2018).

There is no exhaustive list of plus factors, but illustrative examples include a highly concentrated or dominated market; coordinated reporting of inflated prices to an index; the occurrence of price increases despite stable production costs; a common motive to conspire; attendance and communications at trade associations; other high level interfirm communications and/or meetings; the frequency of the unlawful transactions in which the parties engaged; and evidence of an unwillingness by competitors to compete on price.¹⁸

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¹⁸ See, plus factors identified in Hanover Ins. Co. v. First Midwest Bank of Poplar Bluff, No. 20-cv-192, 2021 WL 5331474, at *4 (E.D. Mo. Nov. 16, 2021); In re Salmon, No. 19-cv-21551, 2021 WL 1109128, at *18 (S.D. Fla. Mar. 23, 2021); In re Cattle Antitrust Litig., 2020 WL 5884676, at *6 (D. Minn. Sep. 29, 2020); In re Tyson Foods, 2018 WL 1598670, at *9; In re Pre-Filled Propane Tank Antitrust Litig., 860 F.3d 1059, 1069 (8th Cir. 2017); Mayor & City Council of Baltimore,

A court should not parse each plus factor and view it in isolation; rather, allegations of conspiracy should be viewed as a whole. SD3, LLC v. Black & Decker (U.S.) Inc., 801 F.3d 412, 425 (4th Cir. 2015). The complaint is plausible, and the claims may proceed to discovery if the circumstantial factual allegations and context support the inference that a party, whose participation was essential to the conspiracy, knew of a scheme and engaged in conduct consistent with such knowledge. Little Kids, Inc. v. 18th Ave. Toys, Ltd., No. 18-cv-533, 2020 WL 7264267, at *13 (D. R.I. Dec. 10, 2020).

The State's complaint alleges a conspiratorial agreement to participate in and effectuate the Insulin Pricing Scheme (¶¶ 317, 354, 536), that each Defendant consciously committed to the scheme and engaged in the overt acts necessary to carry it out (¶354, 537), and that the Defendants coordinated with respect to pricing, resulting in lockstep price increases to fund Manufacturer Payments to secure formulary position. (¶92, 115, 186, 275, 354, 369). The State alleges that the conspiracy could not have been accomplished without the willing participation of both the Manufacturers and the PBMs. (¶20, 354, 361).

Moreover, the context of the conspiracy, as plead in the complaint, plausibly suggests a preceding agreement between the Defendants. The Manufacturers control

Md. v. Citigroup, Inc., 709 F.3d 129, 136 (2nd Cir. 2013); *Evergreen Partnering Grp., Inc. v. Pactiv Corp.*, 720 F.3d 33, 48 (1st Cir. 2013).

the production of insulin and are responsible for the manufacture of 99% of insulins sold in Montana. (¶ 246). The insulin pricing system does not function as a normal market in which competition reduces prices (¶¶ 175, 233, 253, 358-359, 374, 429, 517); at least one co-conspirator, OptumRx, has admitted the "lack of meaningful competition" in a market "for a drug that is nearly 100 years old and which has seen no significant innovation in decades." (¶ 358). Plausibility is also evident in the 2021 findings of the 2021 Senate Insulin Committee, which declared that the "[M]anufacturers and [PBMs] have created a vicious cycle of price increases" in an industry that "is anything but a free market …" (¶ 375).

In addition to these undisputed facts, the complaint alleges that the Defendants share confidential and proprietary market data and information (¶354), with frequent and regular arranged meetings between the Defendants' C-suite executives at trade conferences and other locations. (¶¶ 92, 134, 186, 326-328, alleging numerous meetings and communications between Defendants' executives at trade conferences). Notably, distinct increases in the prices of insulin products occurred shortly after industry conferences. (¶¶ 331-332).

Tellingly, in their testimony before Congress, the Manufacturers admitted engaging in the over acts which furthered the conspiracy alleged by the State. (¶ 362, President of Novo Nordisk describing the "perverse" and "misaligned" incentives of the insulin pricing system which "encourage[] keep[ing] prices high"; ¶ 363, Eli

Lilly admission that it raises reported prices as *quid pro quo* for formulary placement). A conspiracy is the only rational explanation for why the price of a one-hundred-year-old drug, which lacks innovation and has not experienced any increase in the costs of production, continues to skyrocket. (¶¶ 253, 358-359, 429, 517). Contextually, the allegations of the complaint paint a picture which demonstrates more than mere parallel conduct.

As other courts have found, the State's factual allegations as a whole plausibly suggest the existence of a preceding conspiratorial agreement. *See, Mississippi,* 2022 WL 3222890, at *8 (Mississippi plausibly alleged the existence of a civil conspiracy); *Harris Cnty.,* 2020 WL 5803483, at *11 ("Harris County does not merely allege parallel conduct; it alleges that both groups of defendants engaged in a *quid pro quo* exchange of rebates for preferred formulary list placement. Harris County pleads facts that suggest a preceding agreement ..."); *Insulin Pricing Litig.,* 2019 WL 643709, at *7 (finding sufficiency of allegations for a RICO conspiracy, "[p]laintiffs do not merely allege parallel conduct, but rather assert facts that suggest a preceding agreement").

Price uniformity, especially if accompanied by an artificial price level not related to the supply and demand of a given commodity, may be evidence from which an agreement or understanding, or some concerted action of sellers operating to restrain commerce, may be inferred. *Triangle Conduit & Cable Co. v. FTC*, 168

F.2d 175, 179 (7th Cir. 1948), *citing Cement Mfrs.' Prot. Ass'n v. United States*, 268 U.S. 588, 606 (1925). Any combination which tampers with price structures is engaged in an illegal activity. *United States v. Socony-Vacuum Oil Co., Inc.*, 310 U.S. 150, 221 (1940).

Even if this Court finds that the State has failed to plausibly plead its conspiracy allegations against the Defendants, such a finding will not resolve the State's claims against the Defendants for their individual violations of the MCPA and for unjust enrichment.

D. Plaintiff's Claims Are Not Barred By Statutes Of Limitation

(1) The Applicable Statutes of Limitation

Foremost, the issue of when a particular plaintiff's cause of action in tort accrued is a question of fact for determination by the jury, with the defendant bearing the burden to prove this affirmative defense. *Sternhagen v. Dow Co.*, 711 F. Supp. 1027, 1031 (D. Mont. 1989); *Thompson v. Nebraska Mobile Homes Corp.*, 647 P.2d 334, 338 (Mont. 1982).

The State agrees that the Montana statutes of limitation applicable to its claims for unfair or deceptive trade practices and unjust enrichment are two (2) and three (3) years, respectively. Mont. Code Ann. § 27-2-211(1)(c) (two year period for MCPA); Mont. Code Ann. § 27-2-202(3) (three year period for unjust enrichment).

Under Montana law, a claim for civil conspiracy adopts the limitations period applicable to the underlying wrongful act. *Sullivan*, 391 P.3d at 68.

MONT. CODE ANN. § 27-2-102(1) provides, in pertinent part, "a claim or cause of action accrues when all elements of the claim or cause exist or have occurred." "Unless otherwise provided by statute, the period of limitations begins when the claim or cause of action accrues." MONT. CODE ANN. § 27-2-102(2). However, "[t]he period of limitation does not begin on any claim or cause of action for an injury to person or property until the facts constituting the claim have been discovered or, in the exercise of due diligence should have been discovered by the injured party if: (a) the facts constituting the claim are by their nature concealed or self-concealing; or (b) before, during, or after the act causing the injury, the defendant has taken action which prevents the injured party from discovering the injury or its cause." MONT. CODE ANN. § 27-2-102(3).

The Montana Supreme Court has applied the discovery rule to latent injuries and matters which are self-concealing due to their complexity. *See, e.g., Draggin'Y Cattle Co., Inc. v. Addink*, 312 P.3d 451, 457 (Mont. 2013). In *Draggin'Y Cattle*, an accountant botched a 1031 tax-deferred property exchange, subjecting the plaintiff to \$2.5 million tax liability. Recognizing the complexity of the 1031 exchange rules, the court applied the discovery rule to allow plaintiff's claim to proceed. "The injury

was concealing in nature by its complexity." *Id*. The pricing structures involved in this action are equally, if not more, complex and self-concealing.

(2) The Discovery Rule Tolls the Statute of Limitations

For purposes of tolling in an action for unfair trade practices, "ordinary diligence" must be exercised by the aggrieved party in the discovery of the facts constituting the deceptive practice. *Osterman v. Sears, Roebuck & Company*, 80 P.3d 435, 441 (Mont. 2003). "[T]he critical determination of when an action accrues is knowledge of the facts essential to the cause of action." *Montana Pole & Treating Plant v. I.F. Laucks & Co.*, 993 F.2d 676, 678 (9th Cir. 1993), *citing Thompson*, 647 P.2d at 469.

In instances where a plaintiff is unaware that he has a cognizable claim, Montana federal and state courts have focused on discovery of causal connection as an essential fact. In *Sternhagen*, 711 F. Supp. at 1031, a plaintiff suffering from cancer filed suit seven years after his diagnosis, alleging injury arising out of exposure to the defendants' herbicide. Finding that plaintiff could not reasonably have become aware "of the connection between" his disease and his exposure to defendants' products until within three years before filing his action, the Court denied the defendants' motion to dismiss on limitations grounds. *Id*.

Likewise, in *Hondo v. PPG Industries, Inc.*, 771 P.2d 956, 961–62 (Mont. 1989), the Montana Supreme Court held that the limitations period began to run

when the plaintiff received a medical opinion linking her injuries to exposure to defendant's paint. Stated differently, the statute of limitations began to run at the point when the plaintiff "discovered" the causal connection between her injuries and her exposure to the paint. *Id.* (emphasis added).

The Manufacturers' attempt to block application of the discovery rule in this action pulls from various sources—sporadic news or opinion articles which mention rebates or question why insulin prices are increasing; testimony given by the Manufacturers' representatives before Congress in an April 2019 hearing (at which representatives of Montana were not present); proposed but vetoed Montana legislation in 2019 which mentions the word "rebates;" and the Montana Pharmacy Benefit Manager Oversight Act ("PBMOA"), codified at MONT. CODE ANN. § 33-2-2401, et seq... The Manufacturers argue that the State, from these sources, should

The 2019 proposed legislation, S.B. 71, 66th Session (Mont. 2019), made no reference to "pharmacy benefit managers" and applied to health insurance issuers. The legislation sought to require health insurance issuers to apply any "rebates"

received for the benefit of plan members. The proposed legislation only mentioned rebates in this regard and it provides no information or facts by which the State could have discerned that the Manufacturers and PBMs are utilizing rebates as a mechanism to artificially inflate and report false list prices for insulin and diabetes medications. *See* https://leg.mt.gov/bills/2019/billhtml/SB0071.htm.

²⁰ Notably, the PBMOA became effective as Montana statutory law in January of 2022, inside of the two-year limitations period applicable to the State's MCPA claims.

Montana's passage of the PBMOA is additionally notable as a milestone in ongoing governmental efforts to pierce opaque Manufacturer-PBM pricing structures. The

have known the facts essential to its claims over two to three years before the filing of this action. Imposing a burden on the State to ferret out causal connection essential to its claims by combing through random news articles and being cognizant of testimony given in its absence asks too—in essence, Manufacturers suggest the State should have exercised "extraordinary" diligence, rather than the ordinary diligence required to invoke the discovery rule. 21 Osterman, 80 P.3d at 441.

Additionally, but without any supporting legal authority, the Manufacturers advance a "borrowing" argument—that the State should have known about the Insulin Pricing Scheme since its Complaint borrows from the allegations of complaints in other actions in which the State was not a party, and that this somehow relates the State's discovery of the Insulin Pricing Scheme back to a time frame of 2017. The Manufacturers' borrowing argument was categorically rejected by the federal court in *City of Miami*, 2022 WL 198028, at *11. The district court in *City of Miami* noted that the defendants cite no case to support this proposition, but more

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PBMOA requires PBMs to make available to the State and Montana health plans never-before-provided disclosures of the rebate amounts and fees which PBMs receive related to therapeutic drug classes. Mont. Code Ann. § 33-2-2406(1)(a-d) & (2). This statute further reflects that the Manufacturer-PBM pricing system is devoid of transparency, and thus, the Montana Legislature appreciated the need to regulate PBMs by means which include forcing disclosure of information.

²¹ Mere knowledge of "rebates" is not enough, and the State's knowledge of the existence of rebates does not absolve the Manufacturers' conduct. *See, Harris Cnty.*, 2020 WL 5803483, at *6.

importantly, the court declined to interpret the reasonable diligence standard for invoking the discovery rule as requiring that "plaintiffs ... trawl [through] court filings across the country for suits involving different plaintiffs with claims that may involve similar facts." *Id.* The district court concluded that the City adequately pled that it could not have discovered the facts giving rise to its claims earlier "because of the opacity of [d]efendants' pricing methods and the [d]efendants' refusal to disclose net prices." *Id.*

To be certain, the pricing structures and mechanisms utilized by the Manufacturers and PBMs are complex and closely-guarded (¶ 456). Pharmaceutical pricing occurs in an opaque network of multiple payment structures which lack transparency. (¶¶ 283, 444, 464). The PBMs are opposed to transparency, contending that pricing structures, including the amounts of rebates they receive, must remain confidential. (¶ 447, testimony of Express Scripts). The Manufacturers do not publicly disclose their actual net-prices or the amount of the rebates they pay. (¶ 457). The Manufacturers and PBMs self-classify the documents relevant to such inquiries as proprietary *via* embedded confidentiality clauses. (¶¶ 458-459). For these reasons, the State and Montana diabetics did not know, and could not have reasonably discovered, the Insulin Pricing Scheme facts essential to their claims in this action before September 2020. (¶ 502).

Issuance of the Senate Insulin Report on January 1, 2022 was a watershed event. The Senate Insulin Report—issued after the Senate's review of thousands of pages of internal documents of the Manufacturers and PBMs—was the first reliable investigative report into insulin pricing and the causal connection between Manufacturer-PBM rebates and fees and escalating insulin prices. (¶¶ 342-343). The Senate Insulin Report established, among other things, (1) that escalating insulin prices are not due to research and development costs or other legitimate market forces, such as supply and demand, and (2) that rebates demanded by the PBMs, and voluntarily paid by the Manufacturers, are the primary culprit in the extreme escalation of insulin prices. Both facts are essential to the State's realization, acting in ordinary diligence, of its claims against the Manufacturers and PBMs for engaging in unfair or deceptive trade practices violative of the MCPA. Any filing by the State before confirmation of these facts by a reliable authority would have been the product of guesswork and potentially violative of FED. R. CIV. P. 11.

(3) Fraudulent Concealment Tolls the Statute of Limitations

For the same reasons that the discovery rule applies—the Manufacturers' and PBMs' history of concealing information that would have revealed the Insulin Pricing Scheme—the doctrine of fraudulent concealment is available to the State. To invoke the doctrine of fraudulent concealment, the plaintiff must plead with particularity the facts giving rise to the doctrine and establish his due diligence in

trying to uncover the facts. *Volk v. D.A. Davidson & Co.*, 816 F.2d 1406, 1416 (9th Cir. 1987). The State has made such showing, as plead in its Complaint and factually elucidated by the State in its argument for application of the discovery rule.

(4) The Continuing Tort Doctrine Tolls the Statute of Limitations

Montana applies the continuing tort doctrine to toll the statute of limitations where the damage is ongoing and has not "stabilized." *Montana Pole*, 993 F.2d at 678, *citing Blasdel v. Montana Power Co.*, 640 P.2d 889 (Mont. 1982). The harm caused by the Insulin Pricing Scheme has not stabilized; the scheme is active and "ongoing," as the Complaint alleges. (¶¶ 471, 483, 513).

The continuing tort doctrine typically involves nuisance or trespass claims, see e.g. Shors v. Branch, 720 P.2d 239, 244 (Mont. 1986), however this Court recently applied the continuing tort doctrine in the context of a constructive fraud claim. Anderson v. Boyne USA, Inc., No. 21-cv-95, 2023 U.S. Dist. LEXIS 29638, at * 9–10 (D. Mont. Feb. 22, 2023) (Morris, J). In Anderson, this Court found that the two-year limitation period for constructive fraud was tolled so long as the harms "continued to accumulate" because the misconduct was ongoing. Id.

In *Gomez v. State*, 975 P.2d 1258, 1263 (Mont. 1999), the Montana Supreme Court noted that it has yet to expand the continuing tort doctrine beyond real property suits so as to not delay running of the limitations period indefinitely. However, the court in *Gomez* never states or even implies that the doctrine could not extend to

actions involving damages to persons or personal property. The State suggests that the incredible lack of diligence of the plaintiff in *Gomez* was a substantial factor which motivated the court to refuse to extend the doctrine. *Id.* at 1263 ("Gomez was aware of his injuries, of the cause of those injuries and of the fact that he had a cause of action ..., yet he did not take action on his claims ..., slept on his rights and should not be rewarded under the law for his lack of diligence."); see also *Anderson*, 2023 U.S. Dist. LEXIS 29638, at * 9–10 (explaining the continuing tort doctrine did not apply, in part, because the plaintiff no longer was experiencing the alleged harm when he filed suit).

Respectfully, the State submits that this action is appropriate for application of the continuing tort doctrine, such that damages which have accrued for unfair and deceptive trade practices since September 2020, and ill-gotten gains which the Defendants have received since September 2019, are recoverable by the State and Montana diabetics.

(5) Regardless of Tolling Doctrines, the Statutes of Limitation have not expired for Injurious Acts which occurred within the Statutory Periods of Limitation

The Ninth Circuit Court of Appeals has held, under the California Unfair Business Practices Act, that its four year statute of limitations does not bar suit to the extent that some of the alleged wrongs occurred within the limitations period. *Betz v. Trainer Wortham & Company, Inc.*, 236 Fed. Appx. 253, 256 (9th Cir. 2007).

Analogously, under antitrust law, each illegal sale of an artificially priced drug to a plaintiff starts the statutory period running anew, regardless of the plaintiff's earlier knowledge – a new cause of action accrues upon each overpriced sale of a drug. *Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 189 (1997). *See also Hennegan v. Pacifico Creative Service, Inc.*, 787 F.2d 1299, 1300 (9th Cir. 1986) ("When an overt act in furtherance of an antitrust conspiracy damages the plaintiff within the limitations period, the plaintiff possesses a cause of action for that damage that is not barred by the statute of limitations.")

The same principle applies to claims for unfair or deceptive trade practices under Montana law. In *Hein*, 353 P.3d at 496, the plaintiff sued his contractor for defective construction and misrepresentations under the MCPA. The plaintiff appealed dismissal of his claim as untimely, arguing that a new consumer protection act claim arose each time the contractor inspected his home and allegedly repaired it in a deceptive fashion. *Id.* at 498. The court found that "[t]o the extent [plaintiff's] complaint alleges separate acts of deception on separate occasions, [his] Consumer Protection Act claims are not limited to the original construction of his home." *Id.* The court held that plaintiff's claims for deceptive acts or practices which occurred within two years of the date of filing of this complaint are not barred by the applicable statute of limitations. *Id.*

Similarly, the court in *In re Jarvar*, 422 B.R. 242, 252 (Bnkr. D. Mont. 2009), applying Montana law, declared that resort to tolling doctrines such as "continuing nuisance" is not necessary under the MCPA where acts or practices by the defendant take place within two years of plaintiff's filing. The defendant in *Jarvar* attempted to collect on an unsecured and invalid Note within two years of plaintiff's filing of an adversary proceeding seeking recovery under the MCPA. Correctly, the court held that plaintiff's claim is not barred by MONT. CODE ANN. § 27-2-211(1).

The State's Complaint alleges acts and conduct, actionable under the MCPA, which have occurred annually to the present date, including years 2019 through 2022. (¶ 13, lockstep raising of prices by the Manufacturer Defendants "over the course of the last fifteen years"); (¶¶ 320-321, 325, meetings and communications between the Manufacturers and PBMs which occur at trade association and industry conferences held "each year"); and (¶ 513, "In furtherance of the Insulin Pricing Scheme, at least once a year for each year during the relevant time period, Defendants reported and published artificially inflated prices for each at-issue drug in Montana …").

In sum, the State's claims are not barred by any statute of limitations. *See also* Plaintiff's Opposition to Pharmacy Benefit Managers' Motion to Dismiss at 15-19, incorporated herein. However, even if none of the tolling doctrines apply, the Defendants cannot escape liability on limitations grounds for harm or damages

which arose from their acts, conduct and practices that occurred since September 2020 for purposes of the State's MCPA claim, and since September 2019 for purposes of the State's unjust enrichment claim.

CONCLUSION

For the foregoing reasons, the PBM Defendants have failed to establish that no claim has been stated upon which relief can be granted, and their Motion to Dismiss should be denied.

If the Court is inclined to dismiss any claims, the State respectfully requests the Court afford the State an opportunity to amend the complaint. *See* FED. R. CIV. P. 15(a)(2) ("The court should freely give leave when justice so requires.").

RESPECTFULLY SUBMITTED this the 31st day of March, 2023.

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Certificate of Service

I hereby certify that on March 31, 2023, I electronically filed the foregoing

with the Clerk of Court using the CM/ECF system which will send notification of

such filing to all counsel of record.

/s/ Josh Wackerly

Josh Wackerly

Certificate of Compliance

I hereby certify that the lines in this document are double spaced, that the type

in this document is proportionally spaced and is in 14-point font, and that this

document consists of a total of 10,642 words, excluding the table of contents, table

of citations, certificate of service, and certificate of compliance.

/s/ Josh Wackerly

Josh Wackerly

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